Summary of Safety and Effectiveness for the EndoLok™

K080317

submitted by
Syntheon LLC
7290 SW 42 Street
Miami, Florida 33155
Phone: (305) 969-4545

APR 29 2008

Contact Person: Carlos Rivera
Device Trade Name: EndoLok™
Common Name: Colonoscope and accessories, flexible/rigid
Classification Name: Endoscopic access overtube, gastroenterology-urology
Regulation Numbwe: 21 CFR § 876.1500

Identification of a Legally Marketed Predicate Device

The Syntheon LLC EndoLok™ is substantially equivalent to EndoEase Advantage™ for Colonoscopy that is legally marketed and distributed by Spirus Medical, Inc. pursuant to premarket notification K062805.

Device Description

The EndoLok™ is a non-sterile, single-use device designed to be used in conjunction with standard colonoscopes. It consists of a handle with a trigger mechanism that is used to grip the colonoscope shaft.

Intended Use

The EndoLok™ is indicated for use as a handle for standard colonoscopies. It is designed to provide a non slip grip to facilitate advancement, retraction, and angular orientation during diagnostic and therapeutic lower GI endoscopy.

Summary of Technological Characteristics

A 7-point comparison of technological characteristics of the Syntheon LLC EndoLok™ and the predicate devices was performed. The devices were found to be substantially equivalent.

Summary of Performance Data

Samples of the Syntheon LLC EndoLok™ were subjected to a 9-point bench test to demonstrate safety and effectiveness. All test samples met each test criterion. The device was determined to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Syntheon LLC
% Mr. Al Weisenborn
Official Correspondent
KMS Medical LLC
7290 SW 42nd Street
MIAMI FL 33155

APR 29 2008

Re: K080317
Trade/Device Name: EndoLok™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: February 1, 2008
Received: February 6, 2008

Dear Mr. Weisenborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): K080317

Device Name: EndoLok™

Indications for Use:

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Prescription Use X (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080317

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